

Product & Regulatory Associates, L.L.C.

August 2, 2005

Ms. Mary L. Waller (PM 21)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency, CM-2
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

Subject: Fireline™ 17 WP Fungicide/Bactericide Agriculture Oxytetracycline,
EPA Reg. No. 80990-1
Application for Pesticide Amendment for Label Change
PRIA Category: R34 Non-Fast Track Changes to Precautionary Label
Statements with Complete Fee Waiver Request

Dear Ms. Waller:

As the authorized representative for AgroSource, Inc., EPA Company No. 80990, I am submitting an application for pesticide amendment for Fireline™ 17 WP Fungicide/Bactericide Agriculture Oxytetracycline, EPA Reg. No. 80990-1. The objective is to amend the existing precautionary label statements based on a primary eye irritation study. The data enclosed supports a Category III and would result in a "Caution" signal word for the product.

This registration submission falls into PRIA Category: R34 non-fast track, changes to precautionary label statements. A complete fee waiver request is also submitted with this application.

The registration application request contains the following enclosed materials:

Volume 1 of 2

Administrative Documents

- Transmittal
- Cover letter
- Registration Application (EPA Form 8570-1)
- Proposed label (One highlighted and 5 plain copies)
- Supporting documentation for fee waiver request (brown envelop)

August 2, 2005

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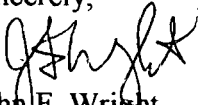
"FlameOut™ 20 WP Primary Eye Irritation Study In Rabbits" U.S. EPA Health Effects Test Guidelines, OPPTS 870.2400, Laboratory Study Number 17645, " July 25, 2005 (3 copies)

466214-01

The test substance used in the primary eye irritation study is the Flame™ 20 WP and is the same formulation as the Fireline 17 WP except the amount of active ingredient was adjusted to a higher value. The FlameOut 20 WP contains 21.57 % w/w oxytetracycline hydrochloride (a minimum 20 % w/w oxytetracycline) while the Fireline 17 WP contains 18.3% w/w oxytetracycline hydrochloride (equivalent to 17% w/w). Therefore, since the higher concentration supports the Category III, it is reasonable to bridge this data to support the same Category III for the lower assay product.

I may be contacted directly at 856.424.1528 or JWrightCH@comcast.net should you have any questions regarding this application.

Sincerely,



John F. Wright

Product & Regulatory Associates, LLC

Authorized Representative of AgroSource, Inc.

cc: Taw W. Richardson, AgroSource, Inc.

RegGuide

January 13, 2004

Document Processing Desk (APPL)
Fungicide Branch
Registration Division
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

ATTN: Mary Waller
Product Manager 21

SUBJECT: APPLICATION FOR PESTICIDE REGISTRATION
RG OTC 17 WP; EPA File Symbol: 74896-U
Response to Agency Letter Dated November 7, 2003

Dear Ms. Waller:

In response to your letter, enclosed please find the following materials in support of the application for registration of the above-subject product:

1. Application for Pesticide Registration
2. Revised Confidential Statement of Formula
3. Revised Draft Labeling (5 copies)

1) There was some confusion regarding the petition for oxytetracycline hydrochloride active ingredient. In a meeting held December 16, 2003, Geo Logic informed EPA that oxytetracycline hydrochloride is CAS # 2058-46-0; the same compound as hydroxytetracycline monohydrochloride, which is the name used in the Reregistration Eligibility Document (RED). Thus, it was agreed between the parties that these are the same compound, that the RED supports oxytetracycline hydrochloride and that data on file related to all registered oxytetracycline-based products can be cited.

2) EPA determined that it could not register the tree injection use due to dissimilarity to the cited product 64014-11. The label has been modified accordingly by removing this use. If RegGuide wishes to pursue these uses it will do so at a later date.

3) EPA determined that it could not register the anti-fouling paint additive use as the product 51946-1 was not reregistered. The label has been modified accordingly by removing this use. If RegGuide wishes to pursue this use it will do so at a later date through the Antimicrobials Review Group.

4) Chemistry requires that one-year storage stability and corrosion characteristics data be submitted. However, EPA indicated that this could be submitted after the registration is granted. These data will be provided to EPA at a later date. Please proceed with the registration process.

5) During the December 16, 2003 meeting, Toxicology and Product Management indicated that they expected to waive and/or cite existing acute studies based on the clarification in item 1) above. However, there was some question expressed about eye irritation. We request the Agency grant this registration without a new eye irritation study at this time. We have revised the signal word to WARNING on the label to address this concern.

6) The Worker Protection Standard (WPS) language regarding waterproof gloves under Personal Protective Equipment (PPE) and in Agricultural Use Requirements has been revised per your letter.

7) The ingredient statement has also been revised on the labeling and a revised CSF has been included per the review of the corresponding application for RG OTC Technical (EPA File Symbol: 74896-L). The Agency determined that the related substances should be indicated on the label in conjunction with the active ingredient.

If you need additional information or have any questions, please do not hesitate to contact me at (636) 942-2583 or e-mail to: Johnston@RegGuide.net.

Sincerely,



Sharon M. Johnston
President

Enclosures

cc: Taw Richardson; Geo Logic

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RegGuide

January 16, 2003

Document Processing Desk (APPL)
Fungicide Branch
Registration Division
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

ATTN: Mary Waller
Product Manager 21

SUBJECT: APPLICATION FOR PESTICIDE REGISTRATION
RG OTC 17 WP; EPA File Symbol: 74896-

Dear Ms. Waller:

Enclosed, please find the following materials in support of the application for registration of RG OTC 17 WP:

1. Application for Pesticide Registration
2. Confidential Statement of Formula
3. Certification with Respect to Citation of Data
4. Data Matrix Sheets
5. Draft Labeling (5 copies)
6. Data Volumes 1 through 3 (3 copies)

This product is substantially similar to Star Brite Distributing's Compound X (EPA Reg. No. 51946-1), Florida Silvics' Tree Tech OTC (EPA Reg. No. 64014-9) and Syngenta Crop Protection's Mycoshield Brand of Agricultural Terramycin (EPA Reg. No. 100-900).

A transmittal document is attached as page two of this letter.

If you need additional information or have any questions, please do not hesitate to contact me at (636) 942-2583 or e-mail to: Johnston@RegGuide.net.

Sincerely,

Sharon M. Johnston, Esq.

Enclosures

